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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0132; FRL-9411-10-OCSPP]

Certain New Chemicals; Receipt and Status Information for October 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to make information publicly available and to publish information in the *Federal Register* pertaining to submissions under TSCA section 5, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 10/1/2022 to 10/31/2022.

DATES: Comments identified by the specific case number provided in this document must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2022-0132, through the *Federal eRulemaking Portal* at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Jim Rahai, Project Management and Operations Division (MC 7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8593; email address: rahai.jim@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 10/01/2022 to 10/31/2022. The Agency is providing notice of receipt of PMNs, SNUNs, and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices. This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, a chemical substance may be either an "existing" chemical substance or a "new" chemical substance. Any

chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a "new chemical substance," while a chemical substance that is listed on the TSCA Inventory is classified as an "existing chemical substance." (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: https://www.epa.gov/tsca-inventory.

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN, or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for "test marketing" purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to:

https://www.epa.gov/chemicals-under-tsca.

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the *Federal Register* certain information, including notice of receipt of a PMN/SNUN/MCAN (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

- D. Does this action have any incremental economic impacts or paperwork burdens?

 No.
- E. What should I consider as I prepare my comments for EPA?
- 1. Submitting confidential business information (CBI). Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at https://www.epa.gov/dockets/commenting-epa-dockets.

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the *Federal Register* after providing notice of such changes to the public and an opportunity to comment (see the *Federal Register* of May 12, 1995 (60 FR 25798) (FRL-4942-7)). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its web site about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCAN and exemption notices received,

the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCAN notices on its web site at:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices. This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.*, domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter "A" (e.g. P-18-1234A). The version column designates submissions in sequence as "1", "2", "3", etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

Table I. – PMN/SNUN/MCANs Approved* from 10/1/2022 to 10/31/2022

Case No.	Version	Received Date	Manufacturer	Use	Chemical Substance
J-22-0019	2	10/3/2022	CBI	(G) Production of a chemical	(G) Saccharomyces cerevisiae, chromosomal integration modification
J-22-0020	2	10/3/2022	CBI	(G) Production	(G) Saccharomyces

				of a chemical	cerevisiae, chromosomal
T 22 0022		0/22/2022	DATE C	(0) 7 1	integration modification
J-22-0022	1	9/23/2022	RWDC Industries	(G) Production of PHA	(G) Microorganisms stably transformed to manufacture PHA
J-22-0023	1	9/23/2022	RWDC Industries	(G) Production of PHA	(G) Microorganisms stably transformed to manufacture PHA
J-22-0024	1	9/23/2022	RWDC Industries	(G) Production of PHA	(G) Microorganisms stably transformed to manufacture PHA
J-22-0025	1	9/23/2022	RWDC Industries	(G) Production of PHA	(G) Microorganisms stably transformed to manufacture PHA
P-16- 0512A	5	9/30/2022	CBI	(S) Component of a UV curable printing inks	(G) Fatty acid dimers, polymer with acrylic acid and pentaerythritol reaction products.
P-17- 0194A	2	10/20/2022	СВІ	(G) Pigment additive for industrial coatings	(G) Hydrogenated dihalo dialkyl diindolotriphenodioxazin e, dihydrodisubstituted isoindolyl alkyl derivs.
P-18- 0070A	11	10/24/2022	Arrowstar, LLC	(G) Chemical intermediate for polyurethane industry	(G) Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids
P-20- 0060A	6	10/6/2022	CBI	(S) Solvent- based pigmented one- and two- component polyurethane coatings Automotive Refinish General Industrial Coil	(G) Bismuth Carboxylate complexes
P-20- 0060A	8	10/20/2022	CBI	(S) Catalyst for polyurethane foam manufacturing	(G) Bismuth Carboxylate complexes
P-22- 0080A	4	10/7/2022	Huntsman International LLC	(S) As an industrial intermediate used in the manufacture of polyamides as a monomer.	(S) Poly(oxy-1,2- ethanediyl), ,'-(iminodi- 2,1-ethanediyl)bis[-(2- aminoethoxy)-;(S) Poly(oxy-1,2-ethanediyl), -(2-aminoethyl)(2- aminoethoxy)-;
P-22- 0121A	3	10/4/2022	CBI	(G) Process Intermediate: New chemical substance will be used as a process intermediate.	(G) polychloroalkene
P-22- 0148A	3	10/27/2022	CBI	(G) Intermediate	(G) Substituted benzonitrile
P-22-	3	10/6/2022	Huntsman	(S) Notified	(S) 2-Propenoic acid, 2-

0153A			International LLC	substance will be used as an adhesion promoter in a resin used for adhesive and/or sealants in industrial assembly or manufacturing operations, in outdoor repair. Through small scale application on assembly line, manual use, or automated use by dispensing unit.	methyl-, 2-hydroxyethyl ester, reaction products with 2-oxepanone homopolymer 2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester and phosphorous oxide (P2O5)
P-22-0175	2	10/26/2022	Wacker Chemical Corporation	(S) Polymer Resin Binder for composite stone (Engineered Stone)	(G) Modified Silsesquioxane, alkoxy- terminated
P-22-0187	2	9/29/2022	LG Energy Solution Michigan Inc	(G) Substance for use in the manufacture of battery components.	(G) Mixed metal oxide
P-22-0192	2	10/11/2022	CBI	(G) Photolithography	(G) Sulfonium, tricarbocyclic-, polyfluoro-heteroatom- substituted polycarbocyclicalkanesul fonate (1:1)
P-23-0001	1	10/3/2022	Solugen Inc.	(G) Additive for consumer, commercial, and industrial applications	(G) Polycarboxylic acid, salt
P-23-0002	1	10/3/2022	Solugen Inc.	(G) Additive for consumer, commercial, and industrial applications	(G) Polycarboxylic acid, salt
P-23-0003	1	10/3/2022	Solugen Inc.	(G) Additive for consumer, commercial, and industrial applications	(G) Polycarboxylic acid, salt
P-23-0004	1	10/3/2022	Solugen Inc.	(G) Additive for consumer, commercial, and industrial applications	(G) Polycarboxylic acid, salt
P-23-0005	1	10/3/2022	Solugen Inc.	(G) Additive for consumer,	(G) Polycarboxylic acid, salt

				commercial, and industrial applications	
P-23-0006	2	10/13/2022	Siltech Inc.	(G) additive	(S) Siloxanes and silicones, di-Me, Me hydrogen, reaction products with vinyl group-terminated di-Me siloxanes
P-23-0009	1	10/5/2022	Givaudan Fragrances Corp.	(G) Fragrance ingredient for use in laundry applications.	(G) Cysteine, cyclic alkyl, ethyl ester
P-23-0010	1	10/5/2022	Givaudan Fragrances Corp.	(G) Fragrance ingredient for use in laundry applications.	(G) Alkylthio ketone
P-23-0011	1	10/10/2022	CBI	(G) Cross- linking agent.	(G) divinylperfluoroalkane
P-23-0012	1	10/11/2022	CBI	(S) Polymer for use in concrete applications.	(G) Starch, polymer with alkenoic acid, salt
P-23-0013	1	10/12/2022	Honeycomb Techno Research USA Inc	(S) Epoxy molding compound for electronic device	(S) Phenol, polymer with 4,4'-bis(chloromethyl)-1,1'-biphenyl
P-23-0015	1	10/26/2022	CBI	(G) Water treatment chemical	(G) Amines, polyalkylenepoly, (disubstitutedcarboxy) derivs., alkali metal salts
P-23-0016	1	10/26/2022	Kuraray America, Inc.	(G) Additive for paints, UV inks, coatings, etc.	(S) 2-Propanol, 1, 3- bis[(3- methyl- 2- buten- 1-yl) oxy]-
SN-21- 0003A	4	10/26/2022	Norquay Technology Inc.	(G) Intermediate	(S) 1,1'-Biphenyl, 4,4'-dibromo-

^{*}The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90 day review period, and in no way reflects the final status of a complete submission review.

In Table II. of this unit, EPA provides the following information (to the extent that such information is not subject to a CBI claim) on the TMEs and/or Biotech Exemptions received by EPA during this period: The EPA case number assigned to the TME and/or Biotech Exemption, the submission document type (initial or amended), the version number, the date the TME and/or Biotech Exemption was received by EPA, the submitting manufacturer (*i.e.*, domestic producer or importer), the potential uses identified by the manufacturer in the TME and/or Biotech Exemption, and the chemical substance identity.

Table II. – TMEs and Biotech Exemptions Received from 10/1/2022 to 10/31/2022

Case	Submission	Version	Received	Manufacturer	Use	Chemical
No.	Type		Date			Substance
T-22-	Test	3	10/4/2022	CBI	(G) Functional	(G) Mica-group
0001A	Marketing				mineral in	minerals, reaction
	Exemption				automotive	products with
	Application				components, and	triethoxysilyl
	(TMEA)				mineral for	substituted-alkane
					plastics	

In Table III of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (e.g., amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

Table III. – NOCs Approved* from 10/1/2022 to 10/31/2022

Case No.	Received Date	Commencement Date	If Amendment, Type of Amendment	Chemical Substance
P-12-0346	10/20/2022	10/17/2022	N	(S) 2-propanone, 2,2',2"-[0,0',0"-(ethylsilylidyne)trioxime]
P-15-0691A	10/7/2022	7/22/2022	Amended generic chemical name	(G) Polyamidoamine n- carbodithioate, sodium salt
P-18-0282A	10/25/2022	10/6/2021	Amended generic chemical name	(G) Fatty acid ester, polyether, poly[di(ethylene glycol) adipate], methylene diphenyl diisocyanate
P-21-0023	10/5/2022	9/7/2022	N	(G) Sulfonium, carbocyclic-, salt with 1-(alkyl) 2-[4-[polyhydro-2-carbomonocyclic-5-(polyfluoro-2-sulfoalkyl)-4,7-methano-1,3-benzodioxol-2-yl]carbomonocyclic oxy]acetate (1:1)
P-21-0068	10/6/2022	9/8/2022	N	(G) Metalloxanes, alkyl, alkyl group-terminated, reaction products with dihalo-dialkylalkylaryl-alkyl-polycyclic-ylidene(dialkylsilylene)-dialkylalkylarylalkylalkyl-polycyclic-ylidene, metal oxide and nonmetallic oxide,
P-21-0085	10/11/2022	9/15/2022	N	(S) 1-propanethiol, 3- (triethoxysilyl)-, reaction products with polybutadiene

^{*}The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table IV of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

Table IV. – Test Information Received from 10/1/2022 to 10/31/2022

Case No.	Received	Type of Test	Chemical Substance
	Date	Information	
P-16-0543	10/14/2022	Industrial Hygiene	(G) Halogenophosphoric acid metal salt
		Exposure Report	
P-21-0011	10/14/2022	Test Scheduling	(G) Hexane, 1,6-diisocyanato-, homopolymer, alkyl
		Notification	epoxy ether- and polyethylene glycol mono-me ether-
			blocked, reaction products with propylenimine

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under FOR FURTHER INFORMATION CONTACT to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 et seg.

Dated: November 21, 2022.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2022-25743 Filed: 11/23/2022 8:45 am; Publication Date: 11/25/2022]